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The Effect of Peripheral Neuropathy on Balance Performance in Community-Dwelling Adults with Type I Diabetes Mellitus

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THE EFFECT OF PERIPHERAL NEUROPATHY ON BALANCE PERFORMANCE IN COMMUNITY-DWELLING INDIVIDUALS WITH TYPE I DIABETES MELLITUS

by

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This Independent Study, submitted by Sonya J. Knutson in partial fulfillment of the requirements for the Degree of Master of Physical Therapy from the University of North Dakota, has been read by the Faculty Preceptor, Advisor, and Chairperson of Physical Therapy under whom the work has been done and is hereby approved.

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PERMISSION

Title:	The Effect of Peripheral Neuropathy on Balance Performance in Community-Dwelling Individuals with Type I Diabetes Mellitus
Department:	Physical Therapy
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Signature Sonya Knutson

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ABSTRACT

Purpose: A common complication of Diabetes Mellitus (DM) is peripheral neuropathy, which may decrease sensory input. The purpose of this study is to determine the correlation between decreased sensation and balance performance.

Methods: Fifty subjects, 25 experimental with Type I DM and 25 control, were recruited from the community. Sensory response was tested with Semmes-Weinstein Monofilaments, and the Berg Balance Measure to assess balance performance. The Pearson correlation and Multiple Regression were performed to study the relationship between DM and balance.

Results: Significance was established between age and 4.31 monofilament response score and the dependent variable, Berg Balance Score. The monofilament score contributed the greatest amount to the prediction equation with a positive beta coefficient of .662; with a higher amount of responses to the monofilament, a higher score on the Berg balance scale can be predicted. Age contributes to the prediction equation to a lesser degree with a negative beta coefficient; as age increases, the Berg balance score is predicted to decrease.

Conclusion: Based on the assumption that neuropathy leads to decreased balance, and that diminished balance increases an individual's risk of falling, our results have shown that the Berg Balance Assessment, used in conjunction with the monofilaments, would be clinically useful in screening a patient with DM for risk of falls.

CHAPTER I

INTRODUCTION

What disease affects the lives of over 12 million Americans, increasing the risk of cardiovascular disease, causing an increased incidence of adult blindness and renal failure, accelerating the aging process, and costing billions of dollars in health care expenditures? Diabetes mellitus (DM), the seventh leading cause of death in the United States.[1]

DM affects an individual's neurological and vascular status, as well as mechanical aspects, all of which play a large role in postural control. A combination of sensory elements is responsible for the detection of body movement, including visual, somatosensory, and vestibular feedback. Neuropathy, a significant decrease in sensory input, is a common complication of DM and is the primary focus of this study.

Problem Statement

There is a need for further research to assess the relationship between peripheral neuropathy and balance performance among the diabetic population. By determining if a significant correlation exists between DM, with or without peripheral neuropathy, and balance performance, effective treatment protocols may be established and prophylactic measures encouraged.

Purpose of Study

This study will address the relationship between neuropathy and an individual's diminished balance, as well as assessing the sensitivity of the Berg Balance Measure when utilized for this patient population. The purpose of this study is to determine the effect of the DM disease process on balance performance.

Significance of Study

Research has shown that postural control is not hardwired, but rather is a flexible skill, which can be improved with training. When automatic postural responses are diminished due to decreased somatosensory input, physical therapy rehabilitation can help patient to learn voluntary postural responses to promote safety and to decrease the risk of falls.

Considering this, it is critical that populations at risk be identified and screened for balance deficits. If it is found that the DM disease process does have a significant effect on balance performance, balance training and prophylactic measures can be initiated. This study will also assess the clinical usefulness of the Berg Balance Measure, used in combination with Semmes-Weinstein Monofilaments, as a screening tool to identify individuals with compromised safety due to decreased balance.

Research Questions

Does diabetes mellitus, with peripheral neuropathy, have a significant effect on balance performance? Does DM itself, without peripheral neuropathy have a significant correlation with balance performance? Does somatosensory input have a significant relationship to postural control?

Hypotheses

Our null hypothesis is that Type I DM, with or without peripheral neuropathy, will have no significant effect on balance performance. Our alternate hypothesis is that there will be a significant correlation between Type I DM, with or without peripheral neuropathy, and balance performance.

CHAPTER II

LITERATURE REVIEW

Balance

Daily tasks and movements frequently challenge our postural control. Often the body's subtle adjustments go unnoticed by the performer. Such adjustments serve to maintain the body's center of gravity (COG) within the base of support (BOS) to allow safe and efficient performance of tasks. Balance control involves anticipating the effect of the environment, as well as self-induced movements, on balance, and then coordinating postural adjustments to minimize the perturbation.[2,3]

Statically, ideal posture can be defined by visualizing a plumbline dropped beside the stationary body. When properly aligned, this vertical line should fall midline between the mastoid process, a point just in front of the shoulder joint, just behind the hip joint, and anterior to the knee and ankle joints. This alignment promotes minimal expenditure of energy, minimizing the effect of gravitational forces tending to pull the body off-center.[2]

Dynamically, postural control requires the appropriate selection of a protective or corrective response to environmental as well as self-induced perturbations. Such selection must occur in a timely manner within the physical constraints of the body.[2,3,4] When balance deficiency exists, the individual is unable to control equilibrium effectively because of neural or biomechanical constraints that cannot be adequately compensated for.

There are three basic strategies used to maintain postural control.[2,9,17] The *ankle strategy* moves the body about the ankle joints while vertical orientation of the trunk is maintained.[16] This strategy requires the ability to feel the supporting surface, as well as adequate ankle strength and range of motion (ROM). It is recruited in response to slow, small perturbations. However, when the distance and velocity of the perturbation increases, the amount of force required to overcome inertia of the body and gravity is greater than what the ankle can provide. The *hip strategy* is then employed, moving the COG quickly, but over a shorter distance than the ankle strategy. By using the hip strategy, rapid corrections can prevent the COG from progressing beyond the limits of stability (LOS).[4,9,18] Finally, when perturbations cause the body's COG to fall outside the LOS, a step is necessary to prevent a fall. This is referred to as the *stepping strategy*. When an individual relies on one strategy and is unable to switch to an alternative strategy more appropriate for the changing task and environment, he or she will experience instability.[5]

Dynamic postural control is highly dependent on sensory input because it detects environmental or positional changes and provides feedback to monitor motor performance.[5,6] Balance utilizes several sensory references including gravity, the surface supporting the body, and the body's relationship to the environment. There are three specific systems involved in maintenance of balance: the *vestibular* organs, the *somatosensory* receptors, and *visual* feedback. The vestibular input provides information about the position of the head in relation to gravity. It is referenced internally to gravitational force rather than to external objects. The somatosensory system relays information according to the support surface, and it informs the brain of the relationship of one body part to another. The visual system reports position of the head in relation to the surrounding environment. This feedback can be deceptive. For instance, at a stoplight when the next car over rolls forward, the brain misinterprets this information and sends a signal to the legs and feet to step on the brake to halt the motion.[2] Under normal conditions, these three systems, in combination, control the body's postural equilibrium via coordinated responses to perturbations. In situations where one system is compromised, such as diabetic neuropathy in the legs or feet causing decreased somatosensory conduction, postural instability may result.[2,4,7]

No one system alone provides adequate and accurate information to the CNS to guide balance control in all circumstances. Postural stability requires the ability of the CNS to weigh the accuracy of sensory input and then appropriately select according to the task and situation. It does appear, however, that under normal conditions, the body places the most emphasis on the somatosensory feedback. [2,8,9,10] However, if the support surface is disturbed, primary emphasis is typically then placed on the visual feedback. [11] In the case that both sensorimotor and visual information are inaccurate, the vestibular system, referenced to gravity, is utilized to resolve sensory conflict.[6,12,13] Because of the redundancy between the sensory systems, the body is able to maintain balance on unstable surfaces, in the absence of vision, or when sensory feedback conflicts. However, if more than one sensory system is inadequate, decreased postural control will be manifest. [5,6,14]

Feedback from the three sensory systems triggers automatic adjustments. These adjustments are employed when unexpected changes in the environment, like a sudden movement of the support surface, occur. When a perturbation is anticipated, preparations, such as increasing the BOS and stiffening the joints through muscular co-contraction, are made. An example of this would be an elderly person seeking handrails prior to ascending stairs. Such preparations are seen more frequently in persons with instability.[3]

Demands on postural control differ according to task and environment, so balance requires continual adaptation. For example, a person sitting in a chair with a large BOS has a large amount of stability, and postural equilibrium is less challenged. However, if a person is standing on a moving bus, there are unpredictable changes occurring and more adaptations are required.[2]

Multiple theories regarding postural control exist. The reflex/ hierarchical theory suggests that balance results from organized reflexive responses. According to this theory, there is development from the primary spinal reflexes to the higher level postural reactions, finally advancing to the mature cortical responses to guide balance.[2,17]

A more recent theory, the systems approach, suggests that balance emerges through interactions with the environment and the tasks performed. This implies that there is a complex interplay between neural and musculoskeletal systems to control the body's position.[2] According to the systems model, balance is a motor skill that results from the interaction of many systems organized to meet functional task demands. Balance is viewed as a skill that, like any skill, can improve with practice within a functional environment.[4] This model proposes that the body is an active participant in a continuously changing environment, rather than solely an organism of reflexes.[19] Skills that the nervous system accomplishes are learned via many systems rather than through reactions to stimuli. Past platform studies have shown that balance performance is adaptive, proactive, and centrally organized based on past experiences and intention. This would support the theory that the nervous system has the ability relearn and benefit from retraining.[4,17]

Diabetes

There are two major types of diabetes- Type I and Type II. "Type I," often referred to as "juvenile-onset" or "insulin-dependent diabetes mellitus (IDDM)", is characterized by the inability of the pancreas to produce insulin, a hormone responsible for glucose homeostasis, which is crucial for life. Without insulin, the body is unable to metabolize sugar. Therefore, insulin treatment is necessary. Although it can potentially be diagnosed at any age, the peak incidence of IDDM is in the early teens.[20] It affects approximately one million Americans and comprises 10-15% of all diabetic cases. [1,21,22]

Type II, otherwise known as "adult-onset" or "non-insulin dependent diabetes mellitus (NIDDM)" is far more common due to the "western" lifestyle as well as genetic predisposition. NIDDM commonly occurs after the age of 30, although it can be diagnosed in children and teens as well. Fifteen percent of the American population over the age of 65 years may have NIDDM.[21,22]

Diabetes is characterized by various complications. These are highly variable between individuals but typically do increase with the duration of DM.[21,23] According to O'Connor et al,[24] the impact of diabetes on physical, social, cognitive, and emotional status is most pronounced in the elderly. These complications are also believed to be associated with poor control of diabetes.[22] Hyperglycemia leads to initial metabolic changes causing nephropathy, retinopathy, and neuropathy. Atheroschlerotic coronary disease is also more common in the diabetic population.[21] Since eye disease is a common complication of DM that could potentially increase the frequency of falls, it must be accounted for in diabetic balance studies. [25]

Peripheral vascular disease (PVD) is a common diagnosis in those with DM. It is typically in the lower extremity (LE) and is more diffuse than non-diabetic PVD, involving bilateral proximal as well as distal arteries.[26] According to Cavanagh and his colleagues, diabetic neuropathy plays a much larger role in LE complications than PVD. They conclude that skin ulceration occurring on the plantar surface of the foot is primarily due to the loss of protective sensation, which prevents the patient from feeling ongoing trauma, rather than due to PVD. Due to lack of sensation, trauma to the feet is not painful and may go unnoticed by the individual. It is this continual trauma that delays the healing of the wound.[27,28]

Neuropathy

Peripheral neuropathy is the most common complication of DM that affects over 50% of the diabetic population who have had the disease for over 25 years.[29] Complications of neuropathy produce symptoms in about 25% of the DM population. Partial or total disability due to the pain or dysfunction affects about 12.5% of all individuals with DM.[30] Pirart[22] states that although electro-physiological abnormalities of the nerve resulting from acute metabolic derangement may be evident at the onset of DM, in about 50% of diabetic patients, *clinically significant* neuropathy will not be evident until after 10 or 15 years of diabetes. This is the result of the abnormal metabolic processes that occur with DM.

The most common type of neuropathy in diabetic patients is *distal symmetrical polyneuropathy*, which affects primarily the LE peripheral nerves and progresses from distal (toes) to proximal (legs). Typically, the loss of sensation occurs in a specific bilateral pattern, commonly referred to as the "stocking glove" distribution.[31] The severity of neuropathy depends on the nerve component affected, as well as individual differences. Therefore, the degree of neuropathy cannot be based exclusively on the duration of the disease.[29]

A study performed by Lord identified the somatosensory system as the most important input in the maintenance of static postural stability at all ages.[32] Simoneau estimated that about 40% of postural control is guided by the somatosensory system. In his study, diabetics with neuropathy proved to be less stable and may therefore have an increased risk of falling due to impaired proprioception. His results indicated that balance control is closely related to the degree of neuropathy.[31]

It is important to take into account, however, that sensory components of the nerve are not exclusively involved. There are also motor and autonomic components of the nerve, which, if affected, can cause posture and gait alterations. Sensory deficit is often the most obvious, including numbness and hyperesthesias (i.e. tingling). Autonomic neuropathy can be noticed in the feet as increased temperature and dry skin. The motor aspect can lead to clawing of the toes and other structural changes.[21,33,34] As a result of neuropathy, distal muscle weakness and atrophy may be apparent along with the increased risk for diabetic ulcers.[21] Without protective pain sensation, stress fractures can occur and go unnoticed. As a result, abnormal weight bearing continues and permanent damage to the foot, such as a Charcots joint, can result.[21,22,26]

Because somatosensory input has been shown to play a significant role in balance performance, increased attention has been given to how sensory deficits, such as neuropathy, can affect balance and gait.[7,22,23,25,29,35,36] Postural movements are chosen based on sensory feedback as well as biomechanical restrictions, so there is a close relationship existing between sensorimotor input and balance. Horak et al[5] concluded in their study that with decreased somatosensory input, subjects were still able to maintain balance but employed different strategies and movement patterns than those without any deficit. The ankle strategy is enhanced by availability of accurate somatosensory input from the supporting surface. When somatosensory information was made unavailable, the hip strategy was adopted in situations where the body would have ideally utilized the ankle strategy. In their study, the subjects were allowed to see the supporting surface and they nevertheless responded as if walking on a narrow beam. This indicates that without sensation in the feet, the subjects were unable to select and manage the ankle strategy.[2,4,5,12]

In familiar settings, there is sensory overlap, so compensation is an unconscious occurrence. Because of these compensations, sensory deficits may not be easily identified until the subject is challenged with conflicting sensory conditions. As an example, if a person, relying heavily on vision to compensate for reduced sensation and proprioception in the ankles, were standing by a bus that started to move, instability could be a result of the inaccurate visual feedback.[4]

Simoneau et al[29] performed a study to determine whether or not diabetic neuropathy has an effect on ankle joint movement perception. Their results showed no significant difference between the ankle joint movement perception in diabetic subjects *without* neuropathy and the non-diabetic controls. However, degradation of sensory input, such as that occurring in those with diabetic neuropathy, resulted in postural instability. Simmons, Richardson, and Pozos' study[7] also showed that IDDM subjects with intact cutaneous sensation (as well as the non-diabetic controls) did not experience the balance deficiencies that existed in the IDDM subjects with decreased sensory input. These findings imply that diabetes in itself is not responsible for balance deficit, but rather diabetic neuropathy. Cavanagh et al[25] concluded that subjects with neuropathy felt significantly less safe during stance and gait in unfamiliar conditions than the control group. Also, these patients with peripheral neuropathy were fifteen times more likely to report an injury such as a fracture, sprained ankle, or cuts and bruises during walking or standing than were subjects with DM but no neuropathy. Most of the limitations resulting from diabetic neuropathy were in the foot and ankle, thereby presumably effecting balance control.

Aging

As the human body ages, subtle changes in the balance-control system have been suggested to occur. Decreased strength,[37] delayed reaction time,[38,39,40] diminished flexibility, faulty posture, decreased peripheral sensation,[40] and impaired balance[19,38] are typical alterations associated with the aging process. Decreases in sensation, perceptual skills, or visual acuity may accentuate these changes.[6,41] According to Peterka and Black, balance deficits are more common among those over the age of 50 years, but that they may be masked due to the redundancy of input. If so, when there is a loss of redundancy, the deficits are then manifested.[38, 42] Both age and disease may contribute to decreased stability among older adults.[8] This deterioration impairs the individual's ability to correct for postural disturbances occurring as a result of daily movements (i.e. turning, reaching, and transferring) and environmental hazards (i.e. throw rugs, ice, etc). These age-related changes could potentially increase the individual's risk of falling.[43,44] Since it has been shown that peripheral limb sensations are the key components to balance at all ages, it becomes increasingly important that, with age, there is a known decrease in visual acuity. If peripheral sensation were diminished, the body would then be less capable of compensation via visual input. However, most falls among the elderly are attributed to inadequate response to postural disturbances,[4] due to the decreased ability to integrate information from all of the sensory systems.[37, 45,46]

Sensory input plays a key role in balance control among the aged. In order to execute the appropriate responses to postural disturbances, integration of the visual, vestibular, and somatosensory systems must occur. Woollacott, Shumway-Cook & Nashner[47] published results stating that with increased age, the neural system becomes less capable of such integration. Another study performed by Kokmen and his coworkers[48] revealed that an increased activation threshold for joint proprioception and cutaneous sensation was associated with the aging process. Considering these recordings, it appears the elderly are placed at a heightened risk of falling. Anacker and Fabio's[46] study results indicate that somatosensory feedback from the ankles is critical in governing body sway. When subjects' balance was tested on a compliant foam surface, the "fallers" were less able to compensate for the conflicting information from the ankles than the "non-fallers" were. The researchers noted that this might be attributed to either decreased strength or due to the increased activation threshold for joint proprioception and cutaneous sensation. They concluded that ankle orientation is a primary determinant of balance control in the elderly. Visual input appears to play a secondary role.[46]

Lord et al[32] also found that decreased proprioception and cutaneous sensation were related to increased postural sway in the elderly. The results of a study by Perrin et al,[37] performed on healthy older adults, confirmed that balance control alterations are indeed induced by aging. They believe that the instability that was noted could reflect slower central integration of the sensory feedback.[37,38] Yet another study on body sway revealed that when sensory information related to balance control was minimized (i.e. closing the eyes), older adults had a larger amount of body sway than did the young adults. These results support the notion that some balance deficiencies do accompany age. It has been shown that diminished LE motor and sensory function in the elderly individual is associated with an increased amount of instability and falls. The DM disease process could accentuate such age-related deterioration.[23]

There is a great amount of heterogeneity among the "aged". A variety of disease processes, medications, and environmental hazards can contribute to decreased balance and falls.[46] We should question how much of the balance deficiencies found in the elderly are due to underlying pathology. It is important to realize that some of the studies on balance in the elderly have been performed in institutions where is it likely that pathologies are at least partially responsible for decreased postural control. The results from these studies cannot be directly applied to elderly persons living independently in the community.[43,45,46,49] According to Lord, one of the greatest difficulties when studying the effect of the aging process on balance and ambulation is the separation of the effects of aging itself and the intermingled disease processes and life-style aspects that accompany the aging process.[32,50]

Medications, environmental perils, and functional insufficiency can lead to an increased number of falls occurring in the elderly.[45] It has been shown that the chance of falling increases linearly with the number of risk factors.[46] Instability may lead not only to increased risk of falling, but also to fear of falls, decreased self-confidence and consequently decreased independence and inactivity.[50] These facts make it increasingly important to do a detailed screening of all participants in a healthy elderly adult study to exclude those with balance-debilitating disease. A specific pre-screening process would also allow characterization of any deficiencies into either an age-related, disease-related, or life style-related causation.[51]

Training

Postural strategies are not a hardwired set of equilibrium reflexes, but rather flexible skills that can be modified by training and experience in new environments. Horak and Nashner[4] believe that the nervous system controls each postural situation according to the specific goal, environmental context, and the task at hand. Perturbation studies performed[52,53] show that with repeated exposure to environmental destabilizing forces, balance strategies become more efficient and effective. As a result of practice, performance is improved, with less effort required.[2] Rehabilitation training can help instill voluntary responses, which though slower than automatic responses can prevent falls in persons with delayed automatic responses due to diminished sensation. When balance is viewed as a motor skill emerging from interaction of multiple system which are organized to meet demands of the environment and task, it seems probable that it should improve with practice. Knowing that training can facilitate improvement in postural control, it is necessary to examine the most effective treatment approach.[4]

Numerous investigations have been undertaken to decide the most effective training methods. Three basic systems contribute to balance so the systems approach suggests training customized to the individual's needs.[13, 54, 55, 56, 57] Past studies[54, 55] have shown that programs targeting specific deficits facilitate significant improvement in balance performance, whereas general programs aimed at total body enhancement failed to show an effect.[8,56, 57]

In Hu and Woollacott's study,[8] older adults improved in postural stability by practicing quiet stance for ten days, one hour per day with sensory information being manipulated selectively. There was a significant training effect noted in their study. Their findings suggest that multi-sensory balance training may be beneficial in improving postural responses to altered somatosensory input. The authors believe that the capability of integrating sensory information was enhanced.

Improvements could be the result of accumulated changes in the neural mechanisms underlying balance control, with potential increased sensitivity at the receptor level in all three systems due to the unusual stimulation such as placing foam below the subjects' feet. Such interventions would prevent normal compensations, possibly forcing other systems to become more responsive. Another explanation may be increased interaction between and better integration of sensory systems. [8]

Hu and Woollacott[8] found that postural control could be improved significantly in older subjects if complex sensory training conditions and specific training programs are applied. Their results imply that sensory integration can be improved, as subjects seemed to learn to re-weight sensory input and select appropriate and reliable information under conditions which unpredictably challenged various systems. Generalized sensory training was shown to be less effective than a specifically designed program aimed at a particular system.

Research has shown that even if the vestibular feedback is accurate and within normal limits, when there is a situation presenting conflicting sensory information from the visual or somatosensory systems, instability may still result in older adults.[17] Several studies have suggested that somatosensory information plays the primary role in balance performance.[10] It is the responsibility of the therapist to determine what constraints the patient has and whether or not there are ways to safely compensate for or reduce such limitations. Clinical evaluation is critical for the development of a specific treatment plan and to establish treatment goals, as well as to accurately document the patient's progress and response to the intervention. Effective treatment of decreased postural control requires that the sensorimotor components of the functional task should be identified. This allows a specific treatment plan to be developed.[17]

Patients with somatosensory deficits may benefit from therapy including an assistive device as well as training to increase reliance on other sensory systems (i.e. vision).[9] It must be considered that while instability may increase the risk of falling, it is not the only factor involved. The therapist should take into account the environmental risk factors as well. Perhaps the patient would benefit from modifications made in the home, such as a raised toilet seat or increased lighting.[48]

A common therapeutic approach to balance retraining is the breakdown of complex tasks into their simple parts. It is frequently accepted that component training will enhance the overall task. For example, a common approach to inefficient weight bearing and gait patterns, such as are seen in hemiplegic adults, is to focus on a less complex task, such as weight shifting, in hopes that it will improve the overall gait cycle. However, Wistein suggests that although balance and locomotion are closely related, improvement in one will not necessarily be accompanied by improvement in the other. She notes that the gait pattern seems to be unaffected by such balance training.[58]

Breaking complex tasks down into their components is believed to be effective only in "long-duration" tasks, such as a wheelchair transfer, in which the patient would benefit from learning a component part, such as locking the wheelchair brakes. The locomotion cycle, on the other hand, is considered to be a "short-duration" task, lasting approximately one second. The separation of one phase (i.e. swing phase) from the other "components" is not a naturally occurring division of the entire gait cycle. Therefore, this breakdown is not necessarily beneficial to the learning of the overall task. Based on these findings, the need to train according to the specific deficiency, rather than a general balance-training program intended to carry over to gait performance, is apparent. [58] Training programs should involve the patient in various functional tasks performed in different types of environmental contexts. This will encourage the adaptable modification of motor processes. To improve an individual's balance, an accurate assessment must be performed to determine any deficiencies present. If the patient shows difficulty in organizing and integrating sensory input, treatment can be based on various (unpredictably changing) conditions requiring utilization of different sensory input. For instance, if a patient is dependent on vision, he or she can practice tasks in low lighting areas or conditions with inaccurate visual input. Shumway-Cook and McCollum[6] state that repetition and practice are crucial components in the modification and compensation process. In patients with sensory deficits, it is important to teach compensation by shifting toward other systems.

CHAPTER III

METHODOLOGY

Subjects

This study consisted of 25 volunteer subjects with Type I Diabetes Mellitus (DM) with or without peripheral neuropathy and 25 age-matched control subjects currently residing independently in the community and surrounding area. Volunteers were recruited from the local area via flyers describing the study, word of mouth, and through a diabetic newsletter. Additional brochures were sent to individuals with DM via a mailing list obtained from a local diabetic support group and the local diabetic association. Subjects responded by phone or by written response to participate in the study.

Inclusion criteria for the experimental group consisted of: Type I DM, age of 18 years or older, ability to comprehend and follow directions, sufficient strength for functional gait without an assistive device, no vestibular disorder, no other neurological disorder (other than diabetes), no amputation, intact skin throughout the lower limb, and no uncorrected visual deficit interfering with functional gait.

The age-matched control group consisted of 25 volunteers without DM who met the rest of the experimental group's inclusion criteria, of which were 15 females and 10 males. Of the 25 subjects in the experimental group, 15 were female and 10 were male. Ages of the subjects (n=50) ranged from 18 to 87 years with a mean of 36.83 years.

Volunteers were excluded from the study if they failed to meet any of the inclusion criteria listed above. Data from two of the volunteers was excluded due to failure to meet the specific predetermined selection criteria. One had a Charcot joint, the other had significant visual deficits interfering with functional gait.

Subjects were informed of the purpose of the study and the testing procedure prior to testing. Each participant was asked to sign an informed consent statement approved by the University or North Dakota Institutional Review Board. (Appendix A)

Instrumentation

The screening instruments used in this study were the Semmes-Weinstein Monofilaments (3.61 and 4.31) and the Berg Balance Measure. Both can be easily administered in the clinic or the client's home.

The Semmes-Weinstein Monofilaments (Appendix B), developed by Sidney Weinstein and Josephine Semmes in the 1960's, were used to test relative thresholds of pressure and touch sensation on the plantar surface of the foot. This test identified those with peripheral neuropathy. Bell-Krotoski reports high reliability (0.84) , validity, and objectivity of the monofilaments, according to standard protocol .[60] Decreased response to stimuli at the predetermined critical level of 4.31was considered a sign of peripheral neuropathy.[61] This is consistent with the North Coast Medical, Inc. instructions for application of the monofilaments, which state that the 4.31 monofilament is used to confirm protective sensation. Traditionally, the 3.61 monofilament, which applies less force due to a smaller diameter, is indicative of normal sensation on the plantar surface of the foot. [62] This tool has been useful for diagnostic purposes, as well as monitoring and predicting direction of neuropathy. [60] Sensation testing with monofilaments are cost-effective when considering both the cost of the instrument and the amount of professional time required for testing.

The Berg Balance Assesment (Appendix C) is an efficient and easily administered balance assessment, requiring only standard household items and 15-20 minutes of time to complete. A stepstool, a 12-inch ruler, and two hard-backed chairs were utilized to complete the Berg Balance Assessment. This test is scored on a 0 to 4 scale (0= inability to perform task, 4=independent) to determine the subject's ability to perform specific tasks, and is frequently used in the clinical setting as an assessment of the patient's functional status. It has good inter-rater reliability (0.98), intra-rater reliabiltity (.99), and content validity amongst the elderly population.[63] Berg et al[63] found that subjects who score below 45 (of 56) are 2.7 times more likely to experience falls than those scoring above 45.[64] In this study, a control group was used for norms to account for the wide variety of ages. Prior to testing, the researchers practiced using these testing procedures on family members and friends to become adept and reliable. All testing was performed in a quiet, well-lit environment free of distractions. Adequate space was ensured for testing purposes and unrestricted movement. Documented, standardized protocols were followed for both assessments.

Procedure

Volunteers were instructed to wear comfortable clothing and walking shoes. Subjects signed an informed consent statement and were then given a survey to identify subjects who met the specific inclusion criteria. (Appendix D) Answers to the brief survey were recorded and discussed. The data of only those subjects who met the inclusion criteria (n=50) were used to obtain the results of this study.

The subject was asked to remove their shoes and socks while sitting on a safe, comfortable chair. Examiner then allowed the subject to feel the pressure of the 3.61 monofilament on his/her hand in order to understand what he/she was feeling for. The procedure was explained to the subject, telling him/her to respond "Yes" if he/she felt the pressure on the foot. It was explained that following the testing of the left foot, the examiner would continue on to the right foot. The subject's lower extremities were then placed upon another chair and the subject was instructed to close his/ her eyes to obliterate visual input while the monofilament testing was performed. Seven specific sites on the plantar surface of each foot (Appendix B) were touched with the 3.61 monofilament. The tester applied enough force to cause the monofilament to bend, at which time the patient would respond "Yes" if he/ she felt the pressure. This procedure was performed three times at each of the seven sites of the foot. If the subject was unable to feel all of the 3.61 monofilament pressures, the procedure was repeated using the thicker, less sensitive 4.31 filament. One researcher recorded the results while the other performed the test. The same researchers performed the Berg Balance and Semmes-Weinstein tests to increase reliability.

Once the Semmes-Weinstein Monofilament Assesment was completed, the subject was instructed to replace his/her socks and shoes in preparation for the Berg Balance Measurement procedure. Standardized protocol was utilized when administering the Berg assessment. (See Appendix C) Throughout this test, one researcher stood within two feet of the subject to guard against falls, while the other researcher administered and scored the performance of each subject. This test measures sitting, standing, and dynamic balance in a variety of conditions, such as standing with eyes closed, turning in a complete circle, functional reach, transferring safely from one chair to another, and stepping onto a footstool. Following this test, subjects were informed of their balance score and any questions or concerns that they had were addressed.

Data Analysis

The independent variables in this study were age of subjects, group (experimental or control), smoking, exercise, 3.61 monofilament response, and 4.31 monofilament response. The dependent variable was the Berg Balance Measure score, indicating balance performance. Multiple regression was utilized to analyze data, with all the variables being entered simultaneously. This was chosen due to multiple variables and limited number of subjects. The Pearson Correlation was used to interpret the data of this study by measuring the degree and direction of linear relationship between two variables. A significance level of $p=.05$ (1-tailed test) was used.

CHAPTER IV

RESULTS

The group of subjects was quite homogenous, showing that 78 percent exercised on a regular basis, eight percent had fallen within the past year, 100% of the experimental group reported that they tested their glucose daily, and two out of the 50 subjects smoked. Ten percent of the subjects subjectively reported less than normal sensation. See Table 1.

Table 1. Descriptives of both groups.

Variable	*Control* (n=25)	*Experimental* (n=25)
Exercise	17	22
Fallen in past year	0	4
Test glucose	NA	25
Smoke	0	2
Foot sensation	Poor=0 Fair=1 Good=24	Poor=0 Fair=4 Good=21

Decreased performance on the higher level dynamic activities of the assessment was evident in both groups. The range of scores in the DM group was 46 to 56. The control group showed increased balance performance with a range of 53 to 56. In Table 2, total Berg Balance Assessment scores are reported for both the diabetic and control groups.

Table 2. Individualized Berg Balance Scores (0-56)

	46	47	48	49	50	51	52	53	54	55	56
DM Group (n=25)	1	0	0	0	1	0	1	1	3	2	16
Control (n=25)	0	0	0	0	0	0	0	1	0	1	23

The mean score on the Berg Balance Assessment was 55.30/ 56. The mean score of total 4.31 monofilament responses (combination score of right and left feet) was 33.64/ 42, the 3.61 monofilament total mean was 23.58. See Table 3 for specific means and standard deviations for both groups.

Table 3. Descriptives of all subjects combined (n=50)

Variables	*Mean* Total	*SD* Total	*Mean* Diabetic	*SD* Diabetic	*Mean* Control	*SD* Control
Age (18- 87)	36.34	18.53	35.96	18.53	36.72	18.91
Total Berg Score (#1-#15) (0-56)	55.30	1.81	54.76	2.39	55.84	0.62
Advanced Berg Activities(#11-#15) (0-20)	15.40	1.48	14.96	1.93	15.84	0.62
Total response to 4.31 monofilament (0-42)	38.64	9.22	35.76	12.37	41.52	1.87
Total response to 3.61 monofilament (0-42)	23.58	13.31	19.92	14.54	27.24	11.05

A regression analysis to determine the effects of age, group, and 4.31 monofilament response on the Berg balance score demonstrated that group identity, control or diabetic, was not a contributor to the Berg balance score ($t = -1.447$, $p = .155$). Thus a second regression analysis was utilized, using the independent variables of age and 4.31 monofilament response.

The results of the second analysis are reported in Table 4 and Table 5. In summary, age is negatively correlated with the Berg balance score; as age increases, balance score decreases. The 4.31 monofilament scores were negatively correlated with the Berg balance scores, predicting that balance scores are better in subjects with increased sensitivity to the monofilament.

Table 4. Correlations (n=50)

		Total Berg Score	Age	Experimental Group (DM)	4.31 Monofilament Total Response
Pearson Correlation	**Total Berg**	1.000	-.613	-.301	.802
	Age	-.613	1.000	-.021	-.413
	4.31	.802	-.413	-.315	1.000
Significance (1-tailed)	**Total Berg**		.000	.017	.000
	Age	.000		NA	.001
	4.31	.000	.001	.013	

The adjusted R^2 (.728) for the model demonstrated that 73% of the variability on the Berg balance score could be predicted by the variables of age and monofilament response. The overall regression analysis was significant ($F=66.65$, $p<.001$). See Table 5.

Table 5. ANOVA

Model		Sum of Squares	df	Mean Square	F	Significanc e
1	**Regression**	118.662	2	59.331	66.650	.000
	Residual	41.838	47	.890		
	Total	160.500	49			

Further analysis of the regression model demonstrated that each of the independent variables, age and 4.31 monofilament response, contributed significantly to the prediction equation. Age was shown to be significant with a Beta coefficient of -.339, t value of –4.149, and a significance of .000. The significance levels associated with 4.31

monofilament response were Beta coefficient of .662, t value of 8.100, and a significance of p=. 000.

In summary, the monofilament score offers the largest contribution to the predication equation; a high score here can be used to help predict a high score on the Berg balance scale. Age also contributes to a lesser degree to the prediction equation with a negative beta coefficient; as age increases, the Berg balance score is predicted to decrease.

To conclude the results of this study, both age of subjects and responses to the 4.31 monofilament significantly contributed to balance performance, showing that an increase in age or decrease in sensation, as tested by monofilaments, correlates with decreased balance performance. According to a Beta Coefficient of -.114, the group (experimental versus control) did not determine balance performance, but rather sensation and age.

CHAPTER V

DISCUSSION/ CONCLUSION

Normal postural control incorporates visual, vestibular, and somatosensory information to maintain the body's center of gravity (COG) over the base of support (BOS). Disruption of one or more of these inputs, such as occurs with peripheral neuropathy in the diabetes mellitus (DM) disease process, results in postural instability.[6] However, this deficit may not be obvious until more than one sensory system is degraded or eliminated. In the present study, the Berg Balance Assessment was performed, which challenges the various sensory systems. The Berg Balance Assessment measures both basic static balance, as well as dynamic balance. The implications of our findings are that diminished cutaneous sensation can lead to decreased postural control, which in turn can lead to falls. Falling is a major cause of morbidity and mortality among the elderly.[50] The consequences of falls are widespread, including economic, psychological, social, and physical. Therefore, it is critical to promote safety with prophylactic interventions, rather than in a curative manner, which requires identification of those at risk. Our results have shown that the Berg Balance Assessment, which is cost-effective, easy to administer, and has excellent reliability and validity, is a choice tool to assess balance performance and to predict safety among the diabetic population.

It was our concern that the Berg Balance may not be sensitive enough to detect small alterations in balance or postural strategies because it was designed to determine safety and risk of falling. However, our results show that it is sensitive enough to pick up a functional deficit. This is adequate for clinical use because in the clinic, our assessment and treatment are focused on functional performance. This includes helping the patient to adapt to the changing task or environmental demands.[3]

The primary results of this study were that decreased cutaneous sensation and diminished balance control were significantly correlated. Also, a significant correlation was found between age and decreased balance performance, as was measured by the Berg Balance Assessment, and a decreased number of responses to the Semmes-Weinstein 4.31 Monofilament, which was indicative of decreased somatosensory input. A regression analysis performed to determine the effect of age, 4.31 monofilament response, and diagnostic group on the Berg Balance score, showed that the diagnostic group alone was not a significant contributor to the Berg Balance score. Although we initially considered the independent variables of smoking, exercise, and 3.61 monofilament response, we were unable to incorporate them into our regression equation as our group was limited in number and very homogeneous. The results of this study were consistent with previous research.[5,7,22,23,25,29,31,32,35]

Lord et al[32] and Simoneau et al[31] found that postural control is highly guided by the somatosensory system. Their results indicated that balance control is very closely related to amount of cutaneous sensory feedback available. Past studies have shown that subjects with DM but without peripheral neuropathy did not exhibit balance deficiencies that were manifest in the peripheral neuropathy group.[7,25,29] These findings, consistent with the results of the present study, suggest that it is not DM per se, but rather diabetic neuropathy that leads to decrease balance performance. This implies that these results can also be applied to peripheral nerve injuries and other diagnoses affecting cutaneous sensation.

The subjects in this study represented a relatively young age group. The results did indicate that sensation and balance performance did decrease as age increased. This was manifest in both the diabetic and the control group. This is consistent with previous studies, which have shown that age does directly impact postural control. It is yet uncertain whether this is primarily due to disease processes that occur more frequently in the elderly, or whether it is due to the aging process itself. In this study, age was not a contributing factor to the results, as age was controlled in the non-diabetic group.

Limitations

It is known that DM can potentially have a deleterious effect on peripheral nerve function. Complications of DM, such as peripheral neuropathy, appear to be highly associated with poor control of the disease as well as with longer duration of DM. It is important to note that subjects in this study were recruited from various support groups or were volunteers from the public and comprised a relatively homogeneous group. It is likely that they are highly motivated individuals who choose to closely monitor and manage their disease. This sample is likely a very well educated and informed group regarding their diagnosis. Therefore, it is likely that those who do not seek regular medical supervision and fail to control blood sugar levels and/or exercise, who chose not to participate in this study or were not informed of the study, would score significantly lower than those participating in our study.

The small sample size utilized and homogeneity of subjects in this study did not allow interpretation of the results beyond correlation. A correlation does not explain why variables are related and cannot be interpreted as a cause-and-effect relationship, because it simply shows a relationship between the variables. Correlation is commonly utilized to predict. If two variables are correlated, the value of one variable can be used to predict the value of the other.[65] Despite this limitation, the Pearson Correlation indicated that there was a significant correlation between the DM group and decreased response to monofilaments and decreased performance on the Berg Balance Assessment. This correlation tends to support the hypothesis that balance is worse in individuals with decreased sensation. Age also showed a significant correlation to Berg scores, as well as monofilament responses.

Clinical Application

It is apparent, from these results that physical therapists need to screen for safety and functional balance within the population with diminished cutaneous sensation. Semmes-Weinstein Monofilaments are a controlled, easy, and non-invasive sensation screening which allows prophylactic care programs to be implemented when indicated. The Berg Balance Assessment is easily administered with basic household items. The results of this study suggest that is would be very useful in the clinic to determine risk of falls and compromised safety in patients with peripheral neuropathy. Based on the assumption that neuropathy leads to decreased balance, and that diminished balance increases an individual's risk of falling, our results have shown that the Berg Balance Assessment, used in conjunction with the monofilaments, would be clinically useful in screening a patient with DM for risk of falls. Also, these tools would be useful in tracking performance throughout therapy.

Once an accurate assessment has been performed to determine if balance deficiencies are present, a training program should be initiated. Previous research performed shows that repeated exposure to environmental destabilizing forces may improve balance strategies. Practice facilitates better performance with less effort required.[2] Rehabilitation training can help instill voluntary responses, which although slower than automatic responses, can prevent falls in individuals with delayed automatic responses due to decreased sensation.[4] Much research has been performed to determine the most successful approach to treatment. The conclusion is that specific training, rather than total body enhancement training, is the most beneficial. Winstein suggests that it is doubtful that component training for balance is successful. She points out that balance training may not carry over to gait, so training should be task specific.[58] It has been suggested that somatosensory input plays the key role in maintaining balance. It may then, be necessary to determine safe ways to compensate to reduce limitations that could compromise safety. This may include encouraging increased reliance on visual input or the use of an assistive device.[6,17] In summary, training programs should advocate using varied functional tasks performed in various environments. This encourages adaptability and modification of motor processes.

APPENDIX A

Subject Consent Form

CONSENT FORM

Sonya Knutson and Laura Eckel, graduate physical therapy students, are performing this study because further research is needed to determine the effect of Type I Diabetes Mellitus on balance and safety in daily living. This research will then be available to improve management of the disease. We invite you to participate in this balance assessment study. We will inform you of any balance deficiencies in comparison to normal scores of persons your age. You have met all specific inclusion criteria for this study. The procedures to be followed include a foot sensation screening to check for peripheral neuropathy resulting in decreased feeling and the Berg Balance Assessment to determine balance abilities. Any discomfort or risk to you is currently unforeseeable in this single session 30-minute assessment. The Berg Balance Measure is a simple and safe test for balance. These motions are ones that are performed routinely in daily activities. You will be asked to perform functional tasks while sitting or standing. Sugar candy will be available if you experience signs or symptoms of hypoglycemia. You will benefit from an increased awareness of balance deficiencies and risks associated with decreased sensation in the lower extremity. All of your assessment scores will remain confidential, as names will be replaced with numbers. If at any time during this study you choose to withdraw from the study, you are free to do so without it being held against you. We are available to answer any questions you have concerning this study. In addition, you are encouraged to ask any questions regarding this study that you may have in the future. Sonya Knutson and Laura Eckel may be reached at (701) 795-3487. Our advisor, Beverly Johnson, may also be contacted at (701) 777-3871. Copies of this consent form are available upon request. In the event that physical injury should occur, medical assistance will be available, as it is to a member of the general public in similar circumstances. Payment for any such treatment must be provided by you and your third party payor, if any (such as health insurance, Medicare, etc.).

"All of my questions have been answered and I am encouraged to ask any questions that I may have concerning this study in the future. I have read all of the above and willingly agree to participate in this study explained to me by the research investigators."

Participant's Signature **Date**

Witness' Signature **Date**

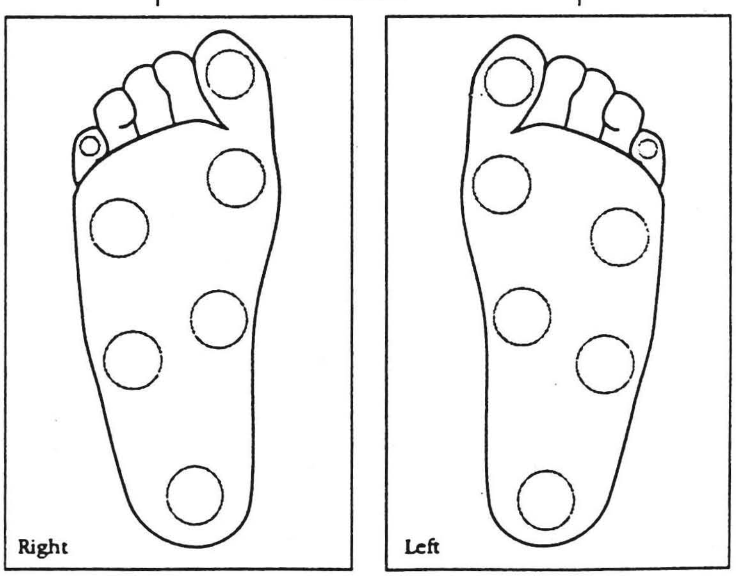
APPENDIX B

Semmes-Weinstein Monofilaments

Patient Foot Screening Form

Monofilament Size	Representation	Plantar Surface Threshold
2.83	Green	Normal (dorsal surface)
3.61	Blue	Normal
4.31	Purple	Diminished Light Touch
4.56	Red	Diminished Protective Sensation
5.07	Red	Loss of Protective Sensation
6.65	Red	Deep Pressure Sensation Only

Plantar



APPENDIX C

Berg Balance Assessment

1. SITTING TO STANDING
INSTRUCTIONS: Please stand up. Try not to use your hands for support.
( ) 4 able to stand without using hands and stabilize independently
( ) 3 able to stand independently using hands
( ) 2 able to stand using hands after several tries
( ) 1 needs minimal aid to stand or to stabilize
( ) 0 needs moderate or maximal assist to stand

2. STANDING UNSUPPORTED
INSTRUCTIONS: Please stand for two minutes without holding.
( ) 4 able to stand safely 2 minutes
( ) 3 able to stand 2 minutes with supervision
( ) 2 able to stand 30 seconds unsupported
( ) 1 needs several tries to stand 30 seconds unsupported
( ) 0 unable to stand 30 seconds unassisted

If a subject is able to stand 2 minutes unsupported, score full points for sitting unsupported. Proceed to item #4.

3. SITTING WITH BACK UNSUPPORTED BUT FEET SUPPORTED ON FLOOR OR ON A STOOL
INSTRUCTIONS: Please sit with arms folded for 2 minutes.
( ) 4 able to sit safely and securely 2 minutes
( ) 3 able to sit 2 minutes under supervision
( ) 2 able to sit 30 seconds
( ) 1 able to sit 10 seconds
( ) 0 unable to sit without support 10 seconds

4. STANDING TO SITTING
INSTRUCTIONS: Please sit down.
( ) 4 sits safely with minimal use of hands
( ) 3 controls descent by using hands
( ) 2 uses back of legs against chair to control descent
( ) 1 sits independently but has uncontrolled descent
( ) 0 needs assistance to sit

5. TRANSFERS
INSTRUCTIONS: Arrange chairs(s) for a pivot transfer. Ask subject to transfer one way toward a seat with armrests and one way toward a seat without armrests. You may use two chairs (one with and one without armrests) or a bed and a chair.
( ) 4 able to transfer safely with minor use of hands
( ) 3 able to transfer safely definite need of hands
( ) 2 able to transfer with verbal cuing and/or supervision
( ) 1 needs one person to assist
( ) 0 needs two people to assist or supervise to be safe

6. STANDING UNSUPPORTED WITH EYES CLOSED
INSTRUCTIONS: Please close your eyes and stand still for 10 seconds.
( ) 4 able to stand 10 seconds safely
( ) 3 able to stand 10 seconds with supervision
( ) 2 able to stand 3 seconds
( ) 1 unable to keep eyes closed 3 seconds but stays safely
( ) 0 needs help to keep from falling

7. STANDING UNSUPPORTED WITH FEET TOGETHER
INSTRUCTIONS: Place your feet together and stand without holding.
( ) 4 able to place feet together independently and stand 1 minute safely
( ) 3 able to place feet together independently and stand for 1 minute with supervision
( ) 2 able to place feet together independently but unable to hold for 30 seconds
( ) 1 needs help to attain position but able to stand 15 seconds feet together
( ) 0 needs help to attain position and unable to hold for 15 seconds

8. REACHING FORWARD WITH OUTSTRETCHED ARM WHILE STANDING
INSTRUCTIONS: Lift arm to 90 degrees. Stretch out your fingers and reach forward as far as you can. (Examiner places a ruler at end of fingertips when arm is at 90 degrees. Fingers should not touch the ruler while reaching forward. The recorded measure is the distance forward that the finger reach while the subject is in the most forward lean position. When possible, ask subject to use both arms when reaching to avoid rotation of the trunk.)
( ) 4 can reach forward confidently 25 cm (10 inches)
( ) 3 can reach forward 12 cm safely (5 inches)
( ) 2 can reach forward 5 cm safely (2 inches)
( ) 1 reaches forward but needs supervision
( ) 0 loses balance while trying/requires external support

9. PICK UP OBJECT FROM THE FLOOR FROM A STANDING POSITION

INSTRUCTIONS: Pick up the shoe/slipper which is placed in front of your feet.

( ) 4 able to pick up slipper safely and easily
( ) 3 able to pick up slipper but needs supervision
( ) 2 unable to pick up but reaches 2-5 cm (1-2 inches) from slipper and keeps balance independently
( ) 1 unable to pick up and needs supervision while trying
( ) 0 unable to try/needs assist to keep from losing balance or falling

10. TURNING TO LOOK BEHIND OVER LEFT AND RIGHT SHOULDERS WHILE STANDING

INSTRUCTIONS: Turn to look directly behind you over toward left shoulder. Repeat to the right. Examiner may pick an object to look at directly behind the subject to encourage a better twist turn.

( ) 4 looks behind from both sides and weight shifts well
( ) 3 looks behind one side only other side shows less weight shift
( ) 2 turns sideways only but maintains balance
( ) 1 needs supervision when turning
( ) 0 needs assist to keep from losing balance or falling

11. TURN 360 DEGREES

INSTRUCTIONS: Turn completely around in a full circle. Pause. Then turn a full circle in the other direction.

( ) 4 able to turn 360 degrees safely in 4 seconds or less
( ) 3 able to turn 360 degrees safely one side only 4 seconds or less
( ) 2 able to turn 360 degrees safely but slowly
( ) 1 needs close supervision or verbal cuing
( ) 0 needs assistance while turning

12. PLACE ALTERNATE FOOT ON STEP OR STOOL WHILE STANDING UNSUPPORTED

INSTRUCTIONS: Place each foot alternately on the step/stool. Continue until each foot has touched the step/stool four times.

( ) 4 able to stand independently and safely and complete 8 steps in 20 seconds
( ) 3 able to stand independently and complete 8 steps > 20 seconds
( ) 2 able to complete 4 steps without aid with supervision
( ) 1 able to complete > 2 steps needs minimal assist
( ) 0 needs assistance to keep from falling/unable to try

13. STANDING UNSUPPORTED ONE FOOT IN FRONT

INSTRUCTIONS: (DEMONSTRATE TO SUBJECT) Place one foot directly in front of the other. If you feel that you cannot place your foot directly in front, try to step far enough ahead that the heel of your forward foot is ahead of the toes of the other foot. (To score 3 points, the length of the step should exceed the length of the other foot and the width of the stance should approximate the subject's normal stride width

( ) 4 able to place foot tandem independently and hold 30 seconds
( ) 3 able to place foot ahead of other independently and hold 30 seconds
( ) 2 able to take small step independently and hold 30 seconds
( ) 1 needs help to step but can hold 15 seconds
( ) 0 loses balance while stepping or standing

14. STANDING ON ONE LEG

INSTRUCTIONS: Stand on one leg as long as you can without holding.

( ) 4 able to lift leg independently and hold > 10 seconds
( ) 3 able to lift leg independently and hold 5-10 seconds
( ) 2 able to lift leg independently and hold = or > 3 seconds
( ) 1 tries to lift leg unable to hold 3 seconds but r remains standing independently
( ) 0 unable to try or needs assist to prevent fall

( ) TOTAL SCORE (Maximum = 56)

APPENDIX D

Subject Survey

Subject Survey

What is your date of birth? ________________

Have you had any fractures in your leg or foot in the past year? **YES or NO**

Do you have any balance disorders (i.e. Meniere's disease) or other factors causing dizziness or instability? **YES or NO**

Do you have visual problems that affect your daily activities? **YES or NO**

How long have you taken insulin? ____________________

Do you use any assistive device (i.e. canes, crutches, walker) for activities of daily living? **YES or NO**

How would you describe your foot sensation? **GOOD FAIR POOR**

Have you suffered from any ulcers or sores on your foot? **YES or NO**
If so, do you currently have an ulcer on your foot or ankle? **YES or NO**

Have you fallen in the past week? **YES or NO** Month? **YES or NO**
Year? **YES or NO** If so, what contributed to your fall(s)? ________________

Do you presently smoke on a daily basis? **YES or NO**

Do you exercise regularly (at least 3 times per week)? **YES or NO**

Do you test your blood glucose level daily? **YES or NO**

Are there any other medical conditions that have not been addressed in this survey that affect your ability to walk? **YES or NO**
If so, please explain.___________________________________

APPENDIX E

IRB Approval

_X_ Expedited Review Requested Under Item _3_ (Number[s] of HHS Regulations)

___ Exempt Review Requested Under Item ___ (Number[s] of HHS Regulations)

UNIVERSITY OF NORTH DAKOTA HUMAN SUBJECTS REVIEW FORM FOR NEW PROJECTS OR PROCEDURAL REVISIONS TO APPROVED PROJECTS INVOLVING HUMAN SUBJECTS

Principal Investigators: Laura Eckel/ Sonya Knutson	Telephone: (701)795-3487	Date: 04/ 29/98
Address to which notice of Approval should be sent: 2169 C South 29th Street, Grand Forks, ND 58201		
School/College: University of North Dakota Department: Physical Therapy	Proposed Project Dates: (Month/Day/Year) 06/01/98- 10/01/98	
Project Title: Influence of Type I Diabetes Mellitus on Standing Balance in Independent, Community-Dwelling Subjects		
Funding Agencies (if applicable):		

TYPE OF PROJECT: NEW PROJECT:_______ CONTINUATION:________

RENEWAL:_______ DISSERTATION OR THESIS RESEARCH _X_ STUDENT RESEARCH

PROJECT:_______ CHANGE IN PROCEDURE FOR A PREVIOUSLY APPROVED

PROJECT:_______

Dissertation/Thesis Adviser: Beverly Johnson

PROPOSED PROJECT INVOLVES NEW DRUGS (IND)______ INVOLVES NON-APPROVED

USE OF DRUG:_______ INVOLVES A COOPERATING INSTITUTION______

IF ANY OF YOUR SUBJECTS FALL IN ANY OF THE FOLLOWING CLASSIFICATIONS,

PLEASE INDICATE THE CLASSIFICATION(S): MINORS (<18 YEARS):_______

PREGNANT WOMEN:_______ MENTALLY DISABLED:______ FETUSES:_______

MENTALLY RETARDED:_______ PRISONERS:_______ ABORTUSES:_______UND

STUDENTS (>18 YEARS):_______

If your project involves any human tissue, body fluids, pathological specimens, donated organs, fetal material, or placental materials, check here: ______

If your project has been/will be submitted to another institutional review board(s), please list name of board(s):

STATUS:____ SUBMITTED; DATE _______ APPROVED; DATE _______ PENDING

1. ABSTRACT:

(Limit to 200 words or less and include justification or necessity for using human subjects.)

The purpose of this proposed study is to determine the effect of the diabetes disease process on balance performance. Balance is affected by a combination of sensory elements responsible for the detection of body motion, including visual, motor, proprioception, and vestibular input. Balance combines stability and mobility to maintain upright stance, with the ultimate goal of safety and function. Diabetes mellitus (DM) affects vascular, neurological, and mechanical aspects, which play a large role in balance. A significant decrease in sensory input is one complication of Type I

DM, which will be the primary focus of this study. Other diabetic changes will be assessed also, to determine their impact on balance. Forty volunteer subjects with insulin-dependent DM will be recruited from the community, support groups, and clinics. Each subject will be an independent individual who meets specific inclusion criteria. Sensory loss will be tested with Semmes-Weinstein Monofilaments. Finally, the Berg Balance Measure will be administered to assess balance. Presently, there is a lack of research relating to balance risks associated with DM. Knowledge of balance risks will encourage prophylactic measures for the DM population.

PLEASE NOTE: Only information pertinent to your request to utilize human subjects in your project or activity should be included on this form. Where appropriate attach sections from your proposal (if seeking outside funding).

2. PROTOCOL:

(Describe procedures to which humans will be subjected. Use additional pages if necessary.)

SUBJECTS: The study will consist of 40 volunteer subjects with Type I Diabetes Mellitus (DM) with or without peripheral neuropathy currently residing independently in the community and surrounding area. Subjects will be recruited via flyers, the diabetic newsletter, and word of mouth. The specific inclusion criteria is: age 18 or older, ability to comprehend and follow requests, sufficient strength for functional gait, no assistive device currently required for daily activities, no vestibular disorders, no other neurological disorders, no severe orthopedic or arthritic problems, no amputations, intact skin throughout lower limb, and no visual problems interfering with daily living.

A voluntary age-matched control group will be recruited and assessed in the same manner as the DM group to establish age-matched norms. The inclusion criteria will be volunteers without DM who meet the rest of the experimental group's inclusion criteria.

Subjects will be informed of the purposes, procedures, and potential risks and benefits of the study. They will then be asked to sign an informed consent statement.

INSTRUMENTATION: The Semmes-Weinstein Monofilaments will be used to test relative thresholds of pressure/ touch sensation on the plantar surface of the foot. This test will identify those with peripheral neuropathy, which will be defined by a critical level. It only requires five minutes to perform. This tool meets sensibility and repeatability requirements for an objective sensory test instrument.

The Berg Balance Measure is an efficient and easily administered balance assessment, requiring only fifteen to twenty minutes to complete. This is scored on the patient's ability to perform specific tasks. The Berg Measure has good inter-rater and intra-rater reliability. Content validity of this measure was established through the manner in which it was constructed.

PROCEDURE: Standard published testing protocols will be followed for all tests. The volunteers will be instructed to wear comfortable clothing and walking shoes. All subjects will be given a survey to identify subjects who meet the inclusion criteria. Each individual will then be asked to sign the informed consent statement. Each participant will lie comfortably on a plinth. A tablet will be held in the patient's line of vision to obliterate his/her vision while the monofilament testing is performed. The response will be charted during the test. Following this, the Berg Balance Measurement procedure will be administered. Each task will be demonstrated and/or instructions given as written. This will test task performance. (See addendum.) The results will be recorded on the Berg Balance Scale Form by an observer during the subject's performance.

Upon request, results of the study will be provided to participants. If subjects show balance deficiency, they will be offered a brochure regarding the prevention of falls.

DATA ANALYSIS: Reliability, means, standard deviations, and ranges will be calculated and recorded, comparing samples within the group utilizing an independent-measures t- test. This analysis will show the correlation between DM and balance performance.

LIMITATIONS OF STUDY: Aging may contribute to balance deficiencies. This limitation is not accounted for, as aging is a complex process involving many aspects of life. To decrease this limitation, we established criteria to eliminate subjects with visual insufficiency, muscle strength inadequate for independent ambulation, and the inability to understand or comprehend commands. As subjects selected will be volunteers only, there is a risk that more compliant, rather than non-compliant, persons will offer to participate in our study. Potentially, the increased compliance could mean less severe progression of DM due to the individual's management of their disease.

Human error during testing will also present a limitation to this study. To lessen this, one tester will consistently perform the testing, while the other person will always score & record the results.

3. BENEFITS:

(Describe the benefits to the individual or society.)

Effective treatment of balance problems requires the understanding of underlying sensory components. This study is intended to determine the relationship between DM and balance. Once this relationship has been identified, specific treatment protocols can be formulated to increase the patient's functional capabilities. In this, physicians, physical therapists, and other health care professionals will benefit. The participants in this study will benefit by becoming more aware of how DM relates to their foot sensation and balance proficiency or deficiency. Prophylactic treatment programs may be encouraged if it is shown that DM does affect balance performance, thereby decreasing the risk of falling during daily activities.

4. RISKS:

(Describe the risks to the subject and precautions that will be taken to minimize them. The concept of risk goes beyond physical risk and includes risks to the subject's dignity and self-respect, as well as psychological, emotional or behavioral risk. If data are collected which could prove harmful or embarrassing to the subject if associated with him or her, then describe the methods to be used to insure the confidentiality of data obtained, including plans for final disposition or destruction, debriefing procedures, etc.)

There are only minimal risks to the individuals participating in this study. The Berg Balance Measure is a simple and safe test for balance. These motions are ones that are performed routinely in daily activities. Subjects will be asked to perform functional tasks while sitting or standing while a tester stands closely by to assist in the event that the subject should lose his or her balance. The risk of hypoglycemia with insulin-dependent diabetes exists, so we will provide sugar candy to alleviate signs and symptoms if they present. The voluntary subjects will be chosen based on health status and willingness to participate.

5. CONSENT FORM:

A copy of the CONSENT FORM to be signed by the subject (if applicable) and/or any statement to be read to the subject should be attached to this form. If no CONSENT FORM is to be used, document the procedures to be used to assure that infringement upon the subjects will not occur.

Describe where signed consent forms will be kept and for what period of time.

The consent form to be used in this study is attached. This will establish the participant's understanding of the study procedures, risks, and benefits. All personal assessment scores will remain confidential, as names will be replaced with numbers, and scores will be kept for five years in a file cabinet in a locked office. All procedures to be used have been determined to be safe and without risk to the patient. We have included numbers to address any questions or concerns that the participants may have following the study.

For FULL IRB REVIEW forward a signed original and thirteen (13) copies of this completed form, and where applicable, thirteen (13) copies of the proposed consent form, questionnaires, etc. and any supporting documentation to:

Office of Research and Program Development

University of North Dakota

Grand Forks, North Dakota 58202-7134

On campus, mail to: Office of Research & Program Development, Box 7134, or drop it off at Room 105, Twamley Hall.

For EXEMPT or EXPEDITED REVIEW forward a signed original and a copy of the consent form, questionnaire, etc. and any supporting documentation to one of the addresses above.

The policies and procedures on Use of Human Subjects of the University of North Dakota apply to all activities involving use of Human Subjects performed by personnel conducting such activities under the auspices of the University. No activities are to be initiated without prior review and approval as prescribed by the University's policies and procedures governing the use of human subjects.

SIGNATURES:

Principal Investigator:	**Date:**
Project Director or Student Adviser:	**Date:**
Training or Center Grant Director:	**Date:**

(Revised 3/1996)

REPORT OF ACTION: EXEMPT/EXPEDITED REVIEW
University of North Dakota Institutional Review Board

DATE: May 28, 1998 PROJECT NUMBER: IRB-9806-315

NAME: Laura Eckel; Sonya Knutson DEPARTMENT/COLLEGE: Physical Therapy

PROJECT TITLE: Influence of Type I Diabetes Mellitus on Standing Balance in Independent, Community-Dwelling Subjects

The above referenced project was reviewed by a designated member for the University's Institutional Review Board on June 1, 1998 and the following action was taken:

☒ Project approved. **EXPEDITED REVIEW** No. 3.
Next scheduled review is on June 1999.

☐ Project approved. **EXEMPT CATEGORY** No. ________. No periodic review scheduled unless so stated in the Remarks Section.

☐ Project approved **PENDING** receipt of corrections/additions. These corrections/additions should be submitted to ORPD for review and approval. **This study may NOT be started UNTIL final IRB approval has been received.** (See Remarks Section for further information.)

☐ Project approval **deferred. This study may not be started until final IRB approval has been received.** (See Remarks Section for further information.)

☐ Project **denied.** (See Remarks Section for further information.)

REMARKS: Any changes in protocol or adverse occurrences in the course of the research project must be reported immediately to the IRB Chairperson or ORPD.

PLEASE NOTE: **Requested revisions for student proposals MUST include adviser's signature.**

cc: B. Johnson, Adviser

Lynn Anderson 6/1/98

Signature of Designated IRB Member Date
UND's Institutional Review Board

If the proposed project (clinical medical) is to be part of a research activity funded by a Federal Agency, a special assurance statement or a completed 310 Form may be required. Contact ORPD to obtain the required documents.

(1/98)

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